## Part 1- Overheads for the EPA 23<sup>rd</sup> Annual National Conference on Managing Environmental Quality Systems

#### April 13-16, 2004 Tampa, Florida

#### **Electronic Tools in Quality Systems Management**

Automated Audit Software for Streamlining On-Site Laboratory Assessments and Managing On-Going Laboratory Performance (Tim Fitzpatrick, Lab-Data Consultants, Inc.)

Applying Electronic Data Checking Tools to Environmental Data (Wayne Word, EarthSoft, Inc.)

Peer Review as a QA Tool for Photo Interpretation (George Brillis, U.S. EPA)

#### **Project Planning and Assessment**

The Transition from DQOs to MQOs for Research Projects (Robert Wright, U.S. EPA)

Greater Consistency of Radiation Emergency Response Analytical Methods Using a Performance Based Approach (Ben Hull, U.S. EPA)

A CD-ROM Based Quality Assurance Project Plan Preparation Tool for Tribes (David Taylor, U.S. EPA)

#### **Electronic Tools for Quality Systems II**

**Electronic Research Notebooks (Shirley Wasson, U. S. EPA)** 

Improved Data Quality Systems Using the Florida DEP Automated Date Processing Tool (ADaPT) and EDMS (Juan Manzano, SFWMD)

The Impact of Electronic Record Regulations on the Pharmaceutical and Chemical Industries Maximize Profit or Comply with Regulations? Good Data Management Software lets you do both

#### **Quality Systems Implementation and Assessment**

Measures of Quality System Implementation (Louis Blume, U.S. EPA)

Performance-Based Management of Environmental Restoration Program (Javier Santillan, Air Force Center for Environmental Excellence)

Office of Pesticide Program Quality System (Betsy Grim, U.S. EPA)

#### **Environmental Data Quality**

What Are Data of Known and Documented Quality? (Marlene Moore, Advanced Systems, Inc.)

**Qualifying Quantification of Measurement Variability (Marcus Kantz, U.S. EPA)** 

Cost-Effective "Collaborative Sampling" in Visual Sample Plan (VSP) Software to Estimate Means and Test Hypotheses (Richard O. Gilbert, Pacific Northwest National Laboratory)

#### **Quality Systems Practices for Research**

ETD QA Core Team: An Eloquent Solution to a Complex Problem (Tom Hughes, U.S. EPA)

ETD Quality Control (QC) Checklist for Research Studies (Mette Schladweiler, U.S. EPA)

QA in Research Laboratories: Rules and Reason (Ron Rogers, U.S. EPA)

## Peer Review as a QA Tool for Photo Interpretation

George M. Brilis,
QA Manager, ESD
John G. Lyon,
Director, ESD
Jeff Worthington
Director OEI QA

23<sup>rd</sup> Annual National Conference on Managing Environmental Quality Systems April 15, 2004



## Research and Development at EPA



- 1,950 employees
- \$700 million budget
- \$100 million extramural research grant program
- 13 lab or research facilities across the U.S.
- Credible, relevant and timely research results and technical support that inform EPA policy decisions





#### Making decisions with sound science requires..

- Relevant, high quality, cutting-edge research in human health, ecology, pollution control and prevention, economics and decision sciences
- Proper characterization of scientific findings
- Appropriate use of science in the decision process

#### Research and development contribute uniquely to..

- Health and ecological research, as well as research in pollution prevention and new technology
- In-house research and an external grants program
- Problem-driven and core research



#### High Priority Research Areas



- Human Health
- Particulate Matter
- · Drinking Water
- · Clean Water
- Global Change
- Endocrine Disruptors
- Ecological Risk
- Pollution Prevention
- Homeland Security

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# Environmental Sciences Division National Exposure Research Laboratory Office of Research and Development US EPA

- ESD has expertise in:
  - Chemistry
  - Remote Sensing
  - Geographical Information Systems
  - Site Characterization



#### Disclaimer

• The information in this document has been funded wholly or by the United States Environmental Protection Agency. It has been subjected to the Agency's peer and administrative review and has been approved for publication. Mention of trade names or commercial products does not constitute endorsement or recommendation by EPA for use. Opinions contained in this article are solely those of the authors and do not reflect the opinions, or the future direction, of the US EPA or the Federal government



## Peer Review as a QA Tool for Photo Interpretation

- Satellite & Aerial Images are eventually "Interpreted"
- Interpretation is "subjective"
- EPA has "Graded Approach"
- EPA has "Categories"
- EPA has a "Peer Review Policy"



## Photo Interpretation The Process

- Shape
- Size
- Pattern
- Tone (Hue)
- Texture
- Shadows

- Shadows
- Site
- Association
- Resolution
- Scale
- Condition of Image Media



#### The "Graded Approach"

 This is a common sense approach that "establishes QA and QC requirements commensurate with the importance of the work, the available resources, and the unique needs of the organization."



#### **QA Categories**

 <u>Category I</u> - include enforcement actions and projects of significant national or congressional visibility. The most rigorous and detailed QA and QC, since the resulting data, information and conclusions, must be both legally and scientifically defensible.



### QA Categories

 Category 2 - These projects are of sufficient scope and substance that their results could be combined with those from other projects of similar scope to produce narratives for making rules, regulations, policies, or laws.



### QA Categories

 Category 3 - produce data, information and conclusions, that are used to evaluate and select basic options, or to perform feasibility studies or preliminary assessments of unexplored areas which might lead to further work.



### QA Categories

 <u>Category 4</u> - produce data, information and conclusions, for the purpose of assessing suppositions. In research, these projects are basic, exploratory, conceptual research to study basic phenomena or issues.



#### Peer Review "Categories"

- One Category.....MAJOR
- Usually, a major scientific and/or technical work product supports a regulatory decision or policy/guidance of major impact. Major impact can mean that it will have applicability to a broad spectrum of regulated entities and other stakeholders, or that it will have narrower applicability, but with significant consequences on a smaller geographic or practical scale.



## Techniques of Validating Photo Interpretation

 Ground Truthing – qualified individual physically carry the results to the location and verify the interpretation by examining the surroundings.



## Techniques of Validating Photo Interpretation

 Informal Peer Review - In this type of peer review, the factors described in the EPA Peer Review Handbook are not always considered. Often, the interpretation is reviewed by management prior to release, with the simple perspective of "does it make sense."



#### Forms of Peer Review

- Soundness of Conclusion
  - evaluation based on a review of the written report.
- Blind Evaluation
  - another scientist is given the same data and metadata and asked to produce their own photo interpretation. The two conclusions are compared.



#### Forms of Peer Review

continued.....

- Internal Review
  - Within an office
    - · Shoulder-to-shoulder
  - Within an organization
    - Includes organizationally-tied personnel (contractors, cooperators, etc)
- Not "Independent" or "Armslength"



#### Forms of Peer Review

continued.....

- External Reviews
  - Journal reviews basically "soundness-of-conclusion"
  - Expert reviews "soundness-ofconclusion" or "blind"
  - University, Corporation,
     Independent consultant "soundness-of-conclusion" or "blind"



## Merging Peer Review & QA Categories

- <u>Category 1</u> Internal (EPA) & external peer review combined with ground-truthing.
- <u>Category 2</u> Internal (EPA) & external (journal) peer review combined with ground-truthing.



## Merging Peer Review & QA Categories (cont....)

- <u>Category 3</u> Internal peer review combined with ground-truthing
- <u>Category 4</u> Internal peer review and/or ground truthing.



#### **Conclusion**

- By using categories to define the type of product, the use of peer review as a tool is realized.
- EPA can substantiate the veracity of the interpretation.
- Managers have a tool to assist in describing type of product and the required level of review.

## Data Quality Objectives and Measurement Quality Objectives for Research Projects

Robert S. Wright
U.S. Environmental Protection Agency
Annual National Conference on Managing
Environmental Quality Systems
April 15, 2004

#### **Abstract**

- Assistance for systematic planning using measurement quality objectives (MQOs)
- MQOs are more familiar to researchers than data quality objectives (DQOs)
- General concepts and techniques
- Cookbook-style procedures are not suggested for diverse research projects
- Examples of error propagation calculations

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#### From Peer Review EPA QA/G-5i

 "...MQOs are not synonymous with project DQOs. DQOs establish the full set of specifications for the design of the data collection effort. The design typically incorporates and specifies requirements for total variability. These requirements are used, in turn, to establish performance criteria, stated as MQOs, for significant components of total variability..."

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#### **DQOs and MQOs**

- DQOs are associated with data users, and MQOs are associated with data collectors
- DQOs function at the level of project goals, while MQOs function at the level of measurement system capabilities
- An iterative process is needed to develop DQOs and MQOs that support each other

#### **Example DQO and MQOs**

- National Ambient Air Quality Standard for ozone
- DQO = < 5% probability of making an incorrect decision based on measurements that indicate an urban area has not attained the standard
- MQOs for ozone measurements
  - < 7% bias based on quarterly audits and
  - < 7% precision based on biweekly checks

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#### Under Ideal Circumstances

- Data users are identified, and their data needs are determined
- DQOs are based on project goals
- Data collectors develop MQOs and estimate funding requirements that allow attainment of DQOs
- Several iterations may be needed to establish a mutually acceptable set of DQOs and MQOs within funding limits

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#### For Research Projects

- · Data users not easy to identify
- No decision to be made
- Difficult to establish requirements for measurement uncertainty
- Measurement uncertainty may not be well characterized
- DQOs and MQOs have to be developed from measurement system capabilities

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#### Natural Sample Variability

- For this discussion, no temporal or spatial sample variability
- In real world, DQOs must take sample variability into account
- To reduce overall uncertainty in a cost-effective manner, first work on largest source of uncertainty (i.e., measurement or sample)

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#### Requirements for MQOs

- They must be realistic, measurable, and auditable
- No generic MQOs that cannot be verified during the project
- Linked to specific quality control check measurements
- Need for mathematical formula for calculating attainment of MQOs
- Auditors can verify MQO attainment

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#### Qualitative DQOs

- "The project intends to produce data that will qualify to receive the 'A' rating with respect to the rating system described in Section 4.4.2 of the <u>Procedures for Preparing Emission Factor</u> <u>Documents</u> (EPA-454/R-95-015)"- ACCEPTABLE
- "For this project, the qualitative data quality objective is to provide data to assess emissions related to the operations of the source."-UNACCEPTABLE

#### **Instrument Performance Specifications**

- Lacking other information, MQOs can be taken from manuals or sales literature
- Specifications must be viewed with skepticism because they may be slanted
- Documented performance evaluation
- Objective, written evaluation procedures
- More credible evidence from independent and objective evaluator

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#### Error Analysis

- Functional relationship between MQOs and DQOs for well-characterized systems
- Statistical techniques estimate total measurement uncertainty
- Assumptions that error sources are known and their variability can be measured and that bias is known and can be controlled

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#### **Error Propagation Techniques**

Addition and Subtraction

$$Q = aX + bY - cZ$$

$$u_c(Q) = \sqrt{\left(as_x\right)^2 + \left(bs_y\right)^2 + \left(cs_z\right)^2}$$

Multiplication and Division

$$Q = aX *(bY/cZ)$$

$$U_c(Q) = (\overline{q})\sqrt{(s_X/\overline{x})^2 + (s_Y/\overline{y})^2 + (s_Z/\overline{z})^2}$$

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#### Statistical Assumptions

- The measurement system components are statistically independent
- The measurements are randomly distributed
- The variances are small so that simplified versions of the equations can be used
- Deviations from these assumptions will lead to errors in estimated uncertainty
- When in doubt, consult a statistician

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#### **Limitations of Error Calculations**

- Dependent on knowing uncertainty of components
- For new measurement systems, uncertainty may not be known
- Empirical techniques can be used (collocated measurements and performance evaluations)
- Individual QC check results can't be substituted for standard deviations in the error calculations

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#### Guide to the Expression of Uncertainty in Measurements (GUM)

- Metrology community has standardized methods for calculating uncertainty
- · GUM accepted by ANSI, NIST, NCSL
- GUM's statistical terminology is different from customary statistical terminology
- GUM provides a defensible method for calculating uncertainty in research projects

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#### **Uncertainty Budgets**

- Given a DQO for total uncertainty, uncertainty limits can be established for each measurement system component
- Project staff can design measurement systems to attain these limits
- Project staff can focus on component that has biggest effect on uncertainty

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## Example 1- Combustion Source Emission Factor

- · Stack gas is pulled through a filter
- · Particulate matter on filter is weighed
- Functional relationship of components

$$EF = \begin{pmatrix} PM_{filter} / \\ / (Q_{Filter} t) \end{pmatrix} \begin{pmatrix} (Q_{dilution} + Q_{\text{Pr}\,obe}) / \\ / Q_{\text{Pr}\,obe} \end{pmatrix} \begin{pmatrix} Q_{Stack} / \\ / Q_{fuel} \end{pmatrix}$$

 Use error propagation techniques to calculate total uncertainty in emission factor

#### **Example 1- Emission Factor**

<b>Measurement Variable</b>	Value	Uncertainty	
Mean mass on the filter	1.2 mg	~ 0.014 mg (1%)	
Flow rate thru filter	8.8 L/min	~ 0.08 L/min (1%)	
Dilution air flow rate	862 L/min	~ 4 L/min (0.5% )	
Sample gas flow rate	20 L/min	~ 0.4 L/min (2%)	
Diluted sample flow rate	882 L/min	~ 4 L/min (0.5% )	
Total stack flow rate	6,000,000 L/min	~ 3000 L/min (2%)	
Fuel flow rate	10 kg/min	~ 0.5 kg/min (5%)	
Sampling time	482 min	~ 2 sec (0.005%)	
Emission Factor	3.5 μg/kJ	~ 0.2 μg/kJ (6%)	

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#### Example 2- Fine Particulates in Air

- · Ambient air is pulled through a filter
- · Filter is weighed before and after sampling
- Functional relationship of components

$$[PM] = (W_e - W_u) / Qt$$

- Total uncertainty calculated from components
- Collocated measurements and performance evaluations used to estimate total uncertainty.

## Example 2- Error Analysis Used to Estimate Total Uncertainty

Measurement Variable	Value	Uncertainty	
Weight of exposed filter	99,412 μg	7.1 μg (0.007%)	
Weight of unexposed filter	99,211 μg	5.7 μg (0.006%)	
Fine particulate mass on filter	201 μg	9.1 μg (~5%)	
Flow rate thru filter	0.015 m <sup>3</sup> /min	0.00045 m <sup>3</sup> /min (3%)	
Sampling time	705 min	2.5 min (~0.03%)	
Fine particulate concentration	19 μg/m³	1.7 μg/m³ (~6%)	

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#### Example 2- QC Checks Used to Estimate Total Uncertainty

Measurement Variable	Value	Uncertainty	
Collocated fine particulate concentrations (precision)	19 μg/m³	1.9 μg/m³ (10%)	
Performance evaluation of flow sensor (index of bias)	0.015 m³/min	0.0015 m³/min (10%)	
Fine particulate concentration	19 μg/m³	2.5 μg/m³ (~14%)	

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#### **Summary**

- Research projects can use MQOs for systematic planning
- DQOs and MQOs should be consistent
- MQOs need to be realistic, measurable, and auditable
- Consider natural sample variability
- Error analysis and uncertainty budgets are useful tools

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#### High Priority Research Areas



- Human Health
- Particulate Matter
- Drinking Water
- Clean Water
- · Global Change
- Endocrine Disruptors
- Ecological Risk
- Pollution Prevention
- Homeland Security

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## Air Pollution Prevention and Control Division

- APPCD is part of ORD/NRMRL
- It conducts research, develops and demonstrates air pollution prevention and control technologies for key industries, electric power plants, incinerators, indoor environments, and sources of greenhouse gases

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## Greater Consistency of Radiation Emergency Response Analytical Methods Using a Performance Based Approach

Ben Hull EPA ORIA John Griggs EPA ORIA

#### 21st Annual National Conference on Managing Environmental Quality Systems April 15, 2004

#### Introduction

- EPA Lessons Learned Report, WTC
  - Emergency Response Infrastructure to Address Both Data Analysis and Information Management
- · Capacity, Comparability, Timeliness of Data
- Agency HSWG, Laboratory Capability and Capacity
  - Multi-Office, Regional Workgroup
  - Addressing a Range of Topic Areas
- Ongoing Work on Radiation Topics
  - Performance Based Approach to Method Development
  - ER Criteria for Assessment of Labs and PT Programs;
     Completing Assessment



#### Goal

- Background on EPA Radiation Program
- Overview of potential ER scenarios
- Outline ER decisions that need to be made
- What is a performance based approach
- MARLAP manual, performance based approach
- Next Steps



#### Background on EPA Radiation Program

- EPA, OAR, Office of Radiation and Indoor Air
- Two laboratories NAREL, R&IENL
- Radiation Protection Division
- Develops Emergency Response Protective Action Guides (PAGs)
- Guidance on risk and dose based decisions for emergency response and site restoration



#### **Overview of Potential ER Scenarios**

- Radiological Dispersal Device
- Improvised Nuclear Device
- Water contamination scenarios
- A range of economic impacts and recovery and remediation issues will need to be addressed



### Outline Decisions that Need to be Made

- Range of decisions over the early, intermediate, and late stages of the event
- Different media, different action levels
- Decisions based on EPA Protective Action Guides; Federal and State Dose and Risk Table



#### Decisions and Associated DQOs

Activity/Decisions	Early	Intermediate	Late
Evacuation			
Evacuation			
Relocation			
Water Control			
Release of Property			
Reentry to Homes			



## MARLAP Manual, Performance Based Approach

- A multi-agency guidance manual for project planners and managers and radioanalytical laboratories
- Participants: EPA, DOE, DHS, NRC, DOD, NIST, USGS, FDA, State Kentucky, State of California
- •To assure that laboratory radioanalytical data meets a program's or project's specific needs and requirements



#### **MARLAP Objectives**

- Providing a framework and an information resource for using a performance-based approach for radioanalytical laboratory work
- Promoting a directed planning process involving radioanalytical laboratory expertise
- Providing guidance on how to link project planning, implementation and assessment from an analytical perspective



### Data Collection Activities Which MARLAP Supports

- Cleanup of Contaminated Sites
- Environmental Monitoring
- ■Waste Management
- Site Characterization
- ■Post-Accident Response
- Background Studies
- Consistent with MARSSIM



#### **DQOs and MQOs**

- •Data Quality Objectives (DQOs)
  - Outputs of a directed planning process
- •Measurement Quality Objectives (MQOs)
  - Project-specific requirement for select analytical parameters (e.g., method uncertainty, detection limits)
  - Analytical portion of the DQOs
  - •MQOs are statements of performance objectives or requirements for a particular analytical method performance characteristic



#### MARLAP MQOs from DQOs

- •An example quantitative MQO, statement of a required method uncertainty at a specified concentration, action level
- •A method uncertainty of .10 pCi/g or less is required at the action level of 1.0 pCi/g



#### **MARLAP MQOs from DQOs**

- •Key inputs to the process
  - •Action level AL
  - •Gray region D
  - •Information on matrix and analyte
- •Establishing MQOS MARLAP provides:
  - •General rules and recommendations



#### Role of MQOs

- •Method selection and evaluation
  - •Criteria for method selection
  - •Basis for method performance demonstration
- Ongoing data and performance evaluation
  - •Criteria for QC and PE sample
  - Criteria for select sample parameters (e.g., measurement uncertainty)
- •Final data evaluation
  - Criteria for data validation
  - •Analytical criteria for data quality assessment (DQA)



## **Use of a Performance Based Approach** and to Produce Comparable Data

- Need During an Emergency to Ensure the generation of radioanalytical data of known quality, appropriate for its intended use
- Need Identified Decision, DQOs
- Need to have upfront appropriate MQOs



#### **Next Steps**

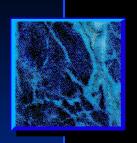
- A robust radiation laboratory network is critically needed to reduce these high potential costs
- Address issue comparable and consistent data to make informed decision
- Very timely reliable data to make informed decisions to reduce these costs



#### **Next Steps**

- Network address range of scenarios, matrices, decisions
- Address data comparability, timeliness issues
- Outputs of Network reduction in radiation exposure to individuals and reduction in significant economic impacts associated lost business productivity, lost tax revenue, and lost property
- Estimated cost impacts are very scenario dependent, but total impacts have been estimated to be in the billions of dollars

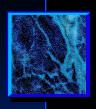




### A CD-ROM Based Quality Assurance Project Plan Preparation Tool For Tribes

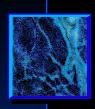
David R. Taylor and Vance Fong

US EPA Region 9 Quality Assurance Office



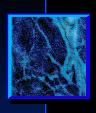
### **Active Workgroup Members** and Affliations

- Roy Araki Region 10 RQAM
- Daniel Chythlook Aleknagik Traditional Council (Alaska)
- Vance Fong Region 9 RQAM
- ☐ Jan Kilduff 29 Palms Band of Mission Indians (Southern California)
- Dan Kusnierz Penobscot Indian Nation (Maine)
- Bessie Lee R9 Tribal Programs Office



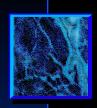
## Workgroup Members and Affliations (continued)

- Melinda Ronca-Battista Tribal Air Monitoring Support (TAMS) Center
- Mary Ellen Schultz Region 3 QA
- Karen E. Stickman Native American Fish and Wildlife Society (Alaska)
- Pat Svetaka Region 1 QA
- David R. Taylor Region 9 QA
- Bruce Woods Region 10 QA



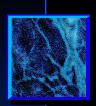
### **Supporting Organizations**

- Regions, especially 1, 3, 9, and 10
- ☐ Tribal Science Council
- Region 9 Tribal Operations Committee
- Quality Staff
- Regional Science and Technology Directors



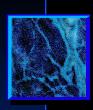
## **Problems Encountered by Tribes Preparing QA Plans**

- Environmental Departments for many tribes are small and inexperienced
- Limited experience with EPA QA System and requirements
- Tribal staff change frequently
- ☐ There is less "institutional memory" than in EPA or state organizations
- ☐ Training often not available, economically feasible, or tribe friendly



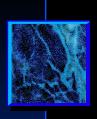
# Problems Encountered by Tribes Preparing QA Plans (continued)

- QA Guidance (general) not tribe friendly
- QA Guidance (program specific) not tribe friendly and varies significantly by program in its availability and detail
- Regions not consistent in requirements and reviews
- Review process too long, difficult, and resource intensive



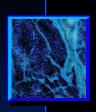
### **General Approach**

- Focus on water monitoring first (hope to expand if time and resources permit)
- CD-ROM based, rather than Internet based
- Regional participation and use of national guidance to help ensure "buy in" from eventual regional reviewers
- ☐ Briefings to RQAMs, RTOC, TSC to encourage feedback



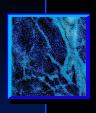
### Status

- Platform
- References
- Template
- Guidance



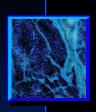
### **Platform**

- Several platforms investigated, none optimal
- ☐ Guidance HTML with Java Script
  - ▲ Links to references
  - ▲ Links to web pages
  - ▲ Navigate using Internet Explorer (free)
  - ▲ Searchable capability



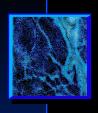
### **Template**

- Follow R-5/G-5 to facilitate "buy in" from Regions
- Limited text, mainly headings with brief description and a few key words
- WordPerfect or Word versions



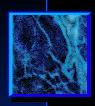
### Guidance

- Goal to minimize QA jargon
- Practical approach
- ☐ Will incorporate list of information tribe should have on hand to start
- Avoid heavy emphasis on "DQO Process"
- May incorporate modified IGDQTF QA tables and checklists



### References

- Will consolidate as many as possible
- Not limited to water
- Variety of formats may be included (e.g., PDF, WP, Word, HTML)
- Analytical Methods via links
- Standard Operating Procedures (SOPs) for straightforward sampling (surface water, etc.)



### **Current Progress**

- Unfortunately, no preliminary version
- Checklist of information completed by end of May
- References being reviewed and consolidated, end of May?
- Template, end of June
- ☐ Guidance and final CD-ROM end of fiscal year

### Electronic Research Notebooks

Shirley Wasson EPA/ORD/NRMRL

Brenda Culpepper EPA/ORD/NHEERL

EPA 23<sup>rd</sup> National Conference on Managing Environmental Quality Systems April 15, 2004

## Research Electronic Notebooks (EN)

- · Research notebooks: paper vs. EN
- Characteristics and advantages.
- EPA's electronic records (ER) experience.
- · Public domain and commercial EN.
- NHEERL experience: research EN.
- · The future for EN and ER.

RESEARCH & DEVELOPMENT

### What are research notebooks?

- Written record of scientific work.
- Repositories of intellectual property.
- Contain notes, raw data, calculations, schematics, photographs, plans, conclusions.



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## What is an electronic notebook (EN)?

A system to create, store, retrieve, and share fully electronic records in ways that meet all legal, regulatory, technical, and scientific requirements.\*

\*Collaborative Electronic Notebook Systems Association (CENSA)

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### Structurally, what is an EN?

- A system of databases, or a number of modules in a single large database.
- Located on a computer or server.
- Accessed via web browser or local area network, password secured.

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### Example EN

- An Oracle database composed of several modules accessed through a Cold Fusion web portal.
- A website written in Perl5 located on a server with WIN NT OS accessed by any web browser.

### A Personal EN

- Keeps project records for noncollaborative research.
- Resides on one computer with limited access.
- · Private until ready to share.
- Instrument and sample log books are other examples of dedicated EN.

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### A Collaborative EN

- The EN of record resides on one computer/server accessed by any authorized person.
- Shared among colleagues (perhaps geographically distant) working on the same project.
- Requires security protocols for access.

### Input to EN Databases

- Direct input from sources such as handheld field instruments, data acquisition systems, and analytical instruments.
- Manual input of data, written matter, sketches, photographs.
- Summary reports, spreadsheets, presentations.

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### EN Usefulness

- Retrieves, calculates, and stores large amounts of data.
- Easily converts files to planning documents, reports, and publications.
- Time- and user-stamps actions for traceability.

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### Paper vs. Electronic

- Inexpensive versus costly.
- One copy versus authorized access to a central copy of record.
- · Scope: limited versus large.
- One person versus possible global collaboration of many.

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### An EN is a record

"Records include all books, papers, maps, photographs, machine readable materials, or other documentary materials. . .made or received by an agency of the United State Government. . .as evidence of the . . .activities. . ."\*

<sup>\*</sup>National Archives and Records Administration (NARA)

### **Functional** Requirements for EN

- Archiveability
- Authenticity
- Retrievability
- Usability
- Security

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### NARA's Timetable

- Established Electronics Records Archives (ERA) program.
- · Will have an operational archive for digital materials by 2007.
- Fully developed by 2011 with online access to an archivist.

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### **EPA's CROMERRR**

- Cross-Media Electronic Reporting and Record-keeping Rule (CROMERRR).
- EPA's proposed electronic record regulations.
- Focus on informing and receiving data from the regulated community.

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### Data Standards

A data standard is a documented agreement among organizations that share or exchange data, including representation, formats, and definitions.\*

\*EPA's Environmental Data Standards Council (EDSC)

### Data standards now out for review

- Provide a common vocabulary for data elements, definitions, format.
- EPA receiving electronic record data via the Central Data Exchange (CDX) from regulated community.
- EPA has not issued policy for research EN.

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### ORD / EIMS

 EPA's Office of Research and Development (ORD) has developed a scientific Environmental Information Management System (EIMS) that stores, manages, and delivers descriptive information (metadata) for data sets, databases, documents, models, multimedia, projects, and spatial information.

### **EIMS**

- Provides a repository for scientific documentation accessible with standard Web browsers.
- EIMS is one of the integrating activities for information management within ORD's OEI.

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### EN Will Feed EIMS

- EIMS is part of a developing research and science architecture (RSA) within EPA.
- Captures the output of EPA's scientific effort including the quality system process.

### OK, so what EN are available?

- Public domain EN: a Department of Energy (DOE) project.
- Commercial EN packages.
- EN synthesized from existing commercial software systems like Microsoft Office or an Oracle database with Cold Fusion access.

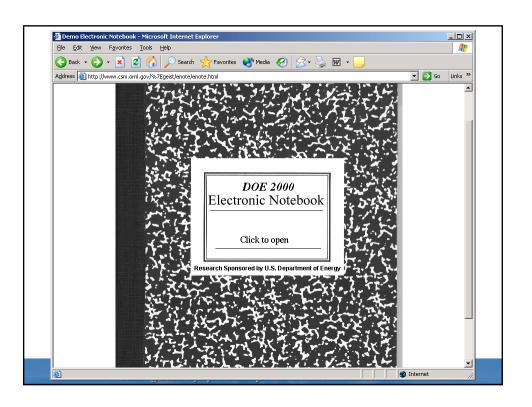
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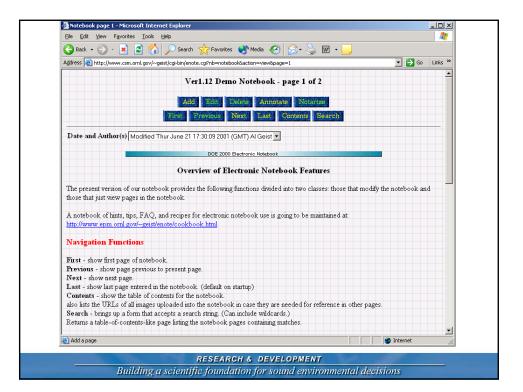
## Example DOE2000 EN Project

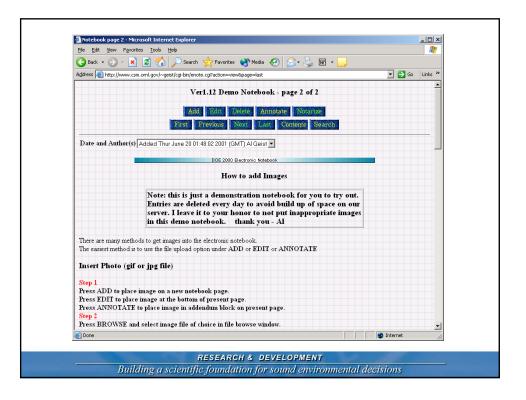
 In 1996, Oak Ridge National Laboratory, Lawrence Berkeley National Laboratory, and Pacific Northwest National Laboratory collaborated to develop an EN architecture and make it available publicly.

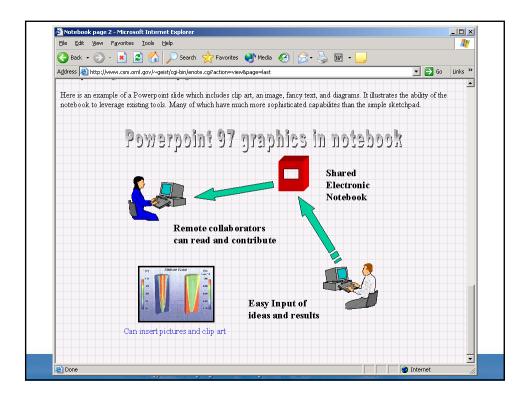
### **Publicly Available**

- Latest DOE EN release Jan 2003.
- 300 groups around the country using and providing feedback.
- Demonstration available at <a href="http://www.csm.ornl.gov/~geist/java/applets/enote/">http://www.csm.ornl.gov/~geist/java/applets/enote/</a>.
- Copy available from Al Geist at gst@ornl.gov.









### Commercial EN Systems

- CambridgeSoft: ChemOffice and E-Notebook.
- NuGenesis: Scientific Data Management System (SDMS) with the Application Control Module (ACM).
- Documentum

### Example NuGenesis

- SDMS captures and stores data from a wide variety of sources (UNIX, Macintosh, Windows).
- Storage in variety of devices (optical disks, CD jukeboxes, storage area network (SAN)).
- Cataloged in Oracle database.

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### **Capabilities**

- Retrieves and archives raw laboratory instrument data files.
- Automatically creates database catalog using predetermined criteria.
- Captures user-created documents, spreadsheets, presentations for later searching.

### **Capacity**

- Runs on Windows platform.
- Fast processing and analysis of data files, inserting metadata in the catalog, then storing.
- Can capture & store 1.5 TB/day.
- 110 million files/527 TB/year.

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### Security

- Responds to FDA regulation of the pharmaceutical industry through 21 CFR Part 11.
- Automatic date & time-stamped data capture.
- Access security and audit trails.
- · Electronic signatures and witnessing.

## Example EN from Existing Software

 Perhaps the most common EN used in EPA today are synthesized from existing software systems like Microsoft Office or Oracle databases with various front ends.

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### Example ORD/NHEERL/MED Research EN

- An aquatic bioassay project monitoring fish exposure to disinfection byproducts of water.
- Fish in 28 aquaria monitored daily for temperature, water flow, and visual observations.
- Fish are periodically sampled, barcoded, tested, and photographed.

### Cold Fusion/Oracle EN

- Data stored in 5 modules in an Oracle relational database.
- Interface is Cold Fusion, which permits access from a web site.
- Data in the modules are linked based on the barcode system.

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### **Data Modules**

- Exposure
- Histology
- Images
- Pathology
- Analytical

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### **Administration**

- IT professional Oracle DB Administrator.
- Project manager (PM) end user administrator.
- Eight users with secure read and write access.

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### **Capabilities**

- Referential integrity via barcode.
- No orphaned records or invalid codes.
- PM selects protocols for each measure.
- Comment fields available for visual observations, sketches.

### Integrity

- Name and time stamp internally recorded on all new records.
- Once saved, entry cannot be modified or deleted.
- Erroneous records marked and documented, then re-entered.
- Printed audit reports provided.

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### Searchability

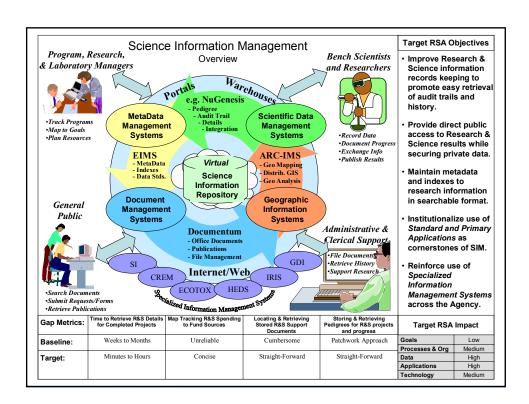
- Access module through website.
- Search using barcode.
- See data: fish, aquarium, conditions, measurements, comments, bioassay reports, photographs.

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### Not Yet Fully Electronic

- Field data sheets still entered by hand.
- Analytical data still kept in paper notebooks.
- Bioassay reports printed daily as a backup permanent record.

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### **Conclusions**

- Research EN are a viable alternative to paper notebooks.
- Represent a significant advance in versatility and capacity.
- Available from public and commercial sources.

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### Conclusions, cont'd

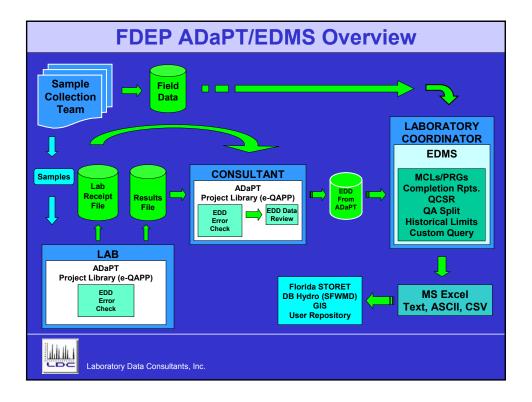
- Keep large amounts of data manageable, organized, search capable, archiveable, sharable.
- Audit-trailed through automated time- and creator-stamped entries, transparent access control, electronic signatures, witnessing.

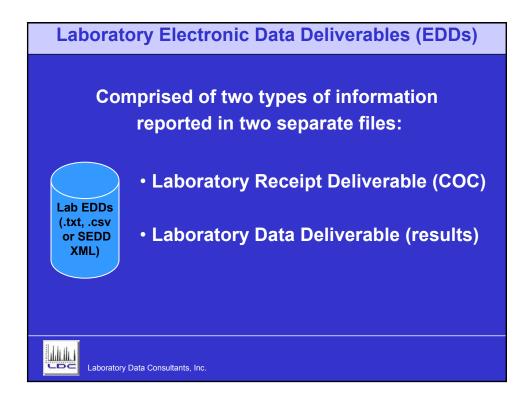
### Next steps

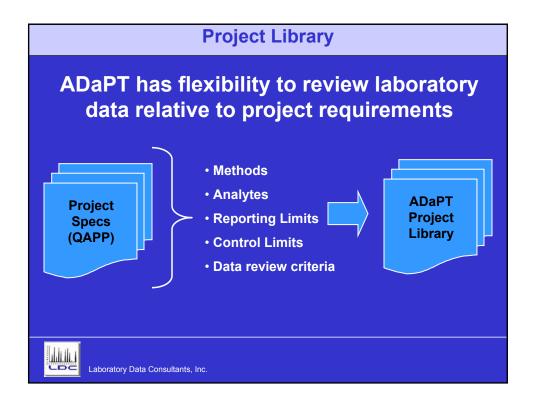
- Integrate the search tools with the data storage tools to provide better interaction (no lost data).
- Increase reliability and userfriendliness.
- · Reduce the cost.

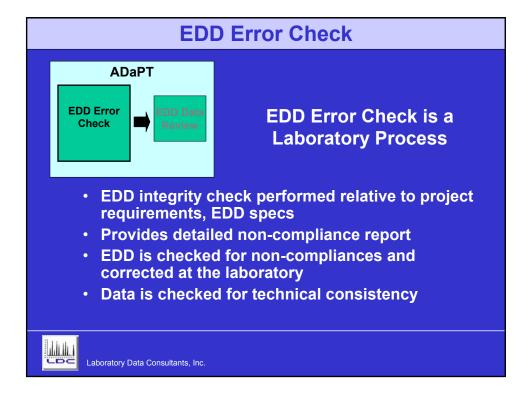
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### **Any Questions?**

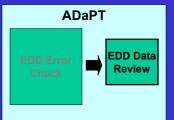








### **Automated Data Review (ADR)**



EDD Data Review is a consultant or lab coordinator function.

- Performs data review
- Evaluates sample results based on linked lab QC samples results such as MB and LCS
- Parent or batch sample qualification for MS/MSD outliers
- Applies data review qualifiers



Laboratory Data Consultants, Inc.

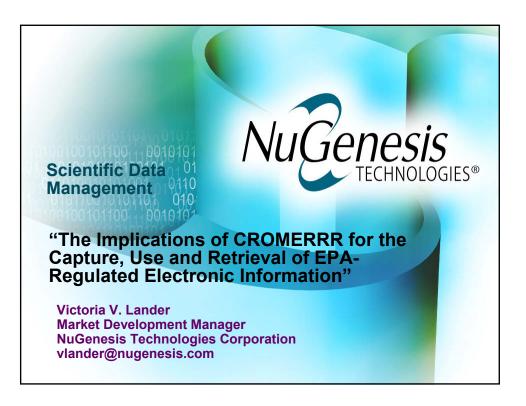
### **Environmental Data Management System**

# EDMS MCLs/PRGs Completion Rpts. QCSR QA Split Custom Query

- Sample tracking
- Compare sample results with regulatory and project specific contamination limits
- Generate QCSR reports
- Compare primary and QA split sample results (RPD and USACE Cold Region schemes)
- Create Project Completion reports.
- Includes a Custom Query Generator for customized data retrieval, and export to third party software.



Laboratory Data Consultants, Inc.



#### **EPA's Thoughts Behind the Rule**



- Create a National Environmental Information Exchange Network
  - A \$100 million, 7 Year Program
  - Modernize and standardize Data Exchange between regulated entities, state agencies and EPA
  - Simplify industry reporting
  - Improve quantity/quality of environmental info EPA provides to us
- Improve Data Integrity, Simplify Filing Procedures and Standardize the Format of Submitted Information
- Goal is to Have States Sending Most Required Data Through the System by December 2004

#### What Is It?



- CROss-Media Electronic Reporting & Recordkeeping Rule
  - A proposed rule
  - 40 CFR Part 3 when final
  - Removes existing regulatory barriers to e-reporting
  - Uses a 'technology neutral' approach
  - Establishes the Central Data Exchange (CDX)
- Proposed 8/31/01
- Comment Period Closed 2/27/02
- Although CROMERRR Resembles Part 11 in Scope, it Differs Significantly in Form and Content

#### What's On Tap for 2004?



- EPA on Schedule to Finalize CROMERRR 3Q FY2004
  - Top Priority of EPA's Office of Environmental Information (OEI)!!!!!
- Agency Still Working On...
  - Ensuring that Authorized Programs at State, Tribal and Local Levels Meet CROMERRR's Goals
  - Establishing Specific Criteria for e-Reporting or e-Recordkeeping
  - Specifying a Process for Certifying that Programs Meet Criteria
  - Streamlining Processes to Review State Programs for e-Reporting
- The Final Rule Will Focus Only on e-Reporting and Defer Coverage of e-Recordkeeping Until Later....
  - In response to public comment

#### What About That e-Reporting?



- For All EPA Regulated Entities
  - e.g. Air, Water, Pesticides, Toxic Substances, Wastes, and Emergency Response
- Removes Existing Regulatory Obstacles to e-Reporting
- Sets Requirements for e-Reporting
- Sets Conditions for Allowing e-Reporting Under State, Tribal, or Local EPA Programs



#### **CROMERRR'S Intends To....**



- Make e-Reporting Easy, Efficient & Cost Effective
- Ensure Transition from Paper to e-Reporting Doesn't Compromise EPA's Compliance and Enforcement Programs
- Impose Few Specific Requirements as Possible
- Keep Requirements Technologically Neutral to Stimulate Adoption of New Technologies
- Not Mandate the Use of e-Media by Regulated Entities
  - But if you choose to make e-submissions, then submissions must meet CROMERRR standards
- Require that Computers Used to Comply Must be Readily Available for, and Subject to, Agency Inspection

#### **CROMERRR WILL NOT Affect...**



- Document Creation, Submission Requirements
- Record Retention Requirements
- Whether the e-Document Must be Signed
- Who is Entitled to Receive Copies
- The Number of Copies that Must be Maintained
- Any Other Requirements Imposed by EPA Regs

Existing provisions of CFR Title 40!!

#### **CROMERRR Components**



- Requirements for Electronically Maintained Records
- Electronic Reporting Requirements
- Capabilities of an e-Record Retention System
- Capabilities of an e-Document Receiving System
- Establishment of a Central Data Exchange (CDX)



#### Voluntary?



- EPA Stressed that this is a Voluntary Rule...
- ...Firms May Choose to Maintain a Paper Based System and Thereby Not be Subject to CROMERRR (!!!!)
  - In the Summary: "The EPA will not require the submission of edocs or maintenance of e-records in lieu of paper docs or records".
  - In the Preamble: "...the choice of using electronic rather than paper for future reports and records will remain purely voluntary".
- BUT.... if You Generate or Maintain Data or Records Electronically, it Definitely WILL Apply



#### Maintenance Requirements for e- Records



- Regulated Entities that Use e-Systems to Create, Modify, Maintain or Transmit e-Records Will Need to Employ Procedures and Controls to Meet the Minimum Criteria
- Criteria are Designed to Ensure that e-Records are:
  - Trustworthy
  - Reliable
  - Available to the EPA
  - Admissible in court to the same extent as paper records



#### Reporting Requirements for e-Records



- E-docs Must be Submitted to an Appropriate EPA
   e-Document Receiving System
- An e-Doc Must be <u>Signed</u> with an e-Sig that can be <u>Validated</u> Using Such a Receiving System
  - Same signing ramifications as signing paper
  - This proposal does not mandate any additional signatures
  - Does NOT specify any required hardware or software





#### **CROMERRR Feedback**



--Ashland Chemical, 2/14/02

- Extremely Broad Scope Makes it Mandatory Even Though it is Described as Voluntary
- The Proposed Criteria for e-Reporting are Complex, Specific and Expensive and Most Existing e-Reporting Systems Will Require Major Upgrading or Replacement
- Costs of Implementation Substantially Underestimated
- Where is the Risk Assessment and Cost/Benefit Analysis?
- EPA Should Withdraw the Proposed Rule and Develop a New Proposal that is Flexible Enough to Incorporate Current Technology and Accommodate Future Advances

#### CROMERRR Feedback



----Comments received from Nancy Dotson, Eastman Corporate Health, Kingsport, TN, 2/26/02

- E-Recordkeeping Portion of the Rule is NOT Voluntary
- The EPA has Significantly Underestimated the Cost Impacts of this Rule
- Firms Would Incur Significant, Unreasonable Costs of Compliance with the Recordkeeping Portion of the Proposal
- eRecordkeeping and Reporting is NOT Already in Place in Most Firms

"It appears that EPA has no understanding of the extensive use in today's world of electronic reporting and recordkeeping. We have great concern that EPA may not appreciate the complexities of records management in this day and age. Businesses are spending millions of dollars on sophisticated data warehousing and other integrated computer technologies that focus on supporting document management and record retrieval capabilities."



#### **Electronic Records**



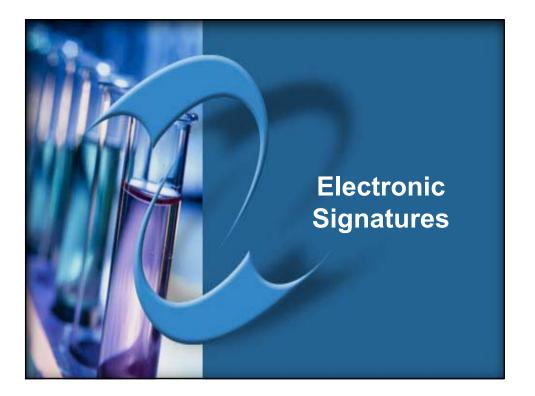
- General Approach that Addresses Record's Integrity, Authenticity and Non-repudiation
- Consistent With Existing Compliance and e-Record Regulations
  - TSCA; FIFRA; GALPs; 21 CFR Part 11
- The Records Addressed are those Maintained in Fulfillment of EPA Compliance Regulations



#### **Electronic Record Requirements**



- Ability to Generate Copies of Records in Human Readable and Electronic Form
- Protections Against Record Compromises
- Use of Secure, Computer Generated Date/Time Stamps and Audit Trails
- Records Can be Readily Retrieved in Normal Course of Business, as Required by the Predicate Regulations
- Records Must be Searchable and Retrievable
- They Must be Archived in Electronic Form Which Preserves the Context, Metadata and Audit Trail



#### **CROMERRR § 3.3 eSig Definition**



- Electronic Signature:
  - "Any Electronic Record that is Incorporated into (or Appended to) an Electronic Document for the Purpose of Expressing the Same Meaning and Intention that an Individual's Handwritten Signature Would Express if Affixed in the Same Relation to the Document's Content Presented on Paper."
- This Differs Considerably in Form to the Definition of "Electronic Signature" Provided in Part 11 § 11.3(7)...
  - "....a Computer Data Compilation of Any Symbol or Series of Symbols Executed, Adopted or Authorized by an Individual to be the Legally Binding Equivalent of His Handwritten Signature."

#### Valid eSignatures



- When Created by a Person Who is Authorized to Sign with an e-sig Device that he is Authorized to Use
- When e-Sig Validated by an e-Doc Receiving System
- The Sig Affixed to a Doc is Proof of Intent to Sign
- EPA Considers the e-Sigs Equivalent to Full Handwritten Sigs…
- ....if e-Records have e-Sigs that Meet CROMERRR Requirements in §3.100(a)(4,5)
- The e-Sig Makes the Signatory Responsible to the Reporting Requirements Like a Handwritten Sig Does
- Similar to Approach Taken by FDA in Part 11 §11.1

#### Signed Retained Records (§3.100)



- An e-Sig Can Substitute for a Full Handwritten Sig if.....
  - An e-record bearing an e-sig contains:
    - The name of the signatory
    - · The date and time of signature
    - · The meaning of the signature
- An e-Sig Affixed to an e-Record is Prevented from Being Detached, Copied, or Otherwise Compromised





#### **Definitions §3.3**



- Electronic Record Retention System Means...
- "Any Set of Apparatus, Procedures, Software, Records or Documentation Used to Retain Exact e-Copies of e-Records and e-Documents."



#### An Acceptable eRecord Retention System Must.. (§3.100)



- Generate and Maintain Accurate and Complete e-Records with Alteration Detection
- Maintain e-Records Without Alteration for the Entire Required Record Retention Period
- Produce Accurate and Complete Copies of any e-Record or e-Document
- Render Copies Available, in Both Human Readable and e-Form, for On-site and Off-site Inspection, for the Entire Record Retention Period
- Any e-Record Bearing an e-Sig Contains the Name of the Signatory, Date/Time of Signature, and the Meaning of the Affixed Signature

# eRecord Retention System Musts (§3.100) Con't



- Prevent an e-Sig Affixed to an e-Record from Being Detached, Copied or Otherwise Compromised
- Use Secure, Computer Generated, Time-stamped Audit Trails that Automatically Record Date/Time of Operator Entries/Actions that Create, Modify or Delete e-Records
- Ensure that Record Changes Do Not Obscure Previously Recorded Information
- That Audit Trails are Retained at Least as Long as Required for the Subject e-Records and Available for Agency Review

# eRecord Retention System Musts (§3.100) Con't



- Ensure that e-Records are Searchable and Retrievable for Reference and Secondary Uses as Required for the Entire Record Retention Period
  - Including inspections, audits, legal proceedings, third party disclosures
- Archive e-Records in e- Form Which Preserves Context, Metadata and Audit Trail
- Must Ensure that......
  - (i) Complete records can be transferred to a new system
  - (ii) Metadata can be transferred to a new system
  - (iii) Functionality necessary for use be reproduced in new system

# eDocument Receiving System (§3.3)



- Definition:
- Any Set of Apparatus, Procedures, Software, Records or Documentation Used to Receive Documents
   Communicated to it via a Telecommunications Network
- For an e-Document to be **Acceptable to EPA** it must be Submitted to an "e-Document Receiving System"
- The e-Document Must Bear Valid e-Signatures



# eDocument Receiving System Musts (§3.2000)



- Ensure that e-Records are Protected from Modification or Deletion
  - Especially once an e-sig has been affixed
- Safeguards to Ensure that System Clock is Accurate and Protected from Tampering
- Robust Precautions Against, and Detect Unauthorized Access or Use, of e-Sigs
- Safeguards to Prevent any other Corruption of the System
- Ensure that Records are Searchable and Retrievable for Secondary Uses Throughout Retention Period
- Archive e-Records in e-Form that Preserves Context, Metadata and Audit Trail
- When Transferring Records, Use Error-checking s/w to Ensure Faithful Transcription of Data

#### eDocument Receiving System Musts Con't



- A Good e-Doc Receiving System Must Also...
- Automatically Create an "e-Copy of Record" of the Submitted Report that...
  - Can be viewed in human readable format
  - Includes the date/time of receipt
  - Has an affixed e-sig
  - Is archived in a compliant system
  - Made available to the submitter for viewing and downloading
  - Is protected from unauthorized access



#### **Submitter Registration**



- You Must First Register with EPA Before Submitting an e-Doc to a Receiving System
- Registration Process Must ...
  - Establish identity of the submitter
  - Establish the ID of the entity they represent
  - Establish that he is authorized to submit
- Must Sign an "e-Sig Agreement" to Properly Use and Protect e-Sigs



#### The Central Data Exchange (CDX)



- CDX is in Response to States' Requests that EPA Assume Burden of Data Collection
- States and Industry Want a Common Point of Exchange with EPA
- It's a Portal Designed to Accept Data from State Environmental Agencies in Several Formats
  - e.g. Word processing docs, spreadsheets, Web forms, e-data interchange files and extensible markup language files
- An Integrated System To....
  - Support the e-reporting needs of more than 14,000 users in 6 major EPA media programs
  - For all significant environmental data collection
  - Accept variety of formats



# **Electronic Records Management Requirements for Organizations**



- Global E-Policy
- Define Responsibilities
- Processes and Procedures
- Implementation
- Digital Environment & Framework
- Integration into Business Process
- Validated Environment
- Monitoring, Audit



#### Requirements For e-Records



- Authenticity
- Reliability
- Integrity
- Usability
  - i.e. retrievable, readable, interpretable



#### ISO 15489: February 5, 2002



- A Guidance for Developing e-Standards for CROMERRR
- Truly an Int'l Records Management Standard
  - Experts from Europe, North America, Asia and Australia agreed on systematic approach to recordkeeping
- Developed by ISO Technical Committee: ISO/TC 46
  - Information and Documentation & Subcommittee 11, Archives/records Management
- EPA Regulated Firms Should Adopt Parts of ISO 15489 for Records Management
- Consists of Two Parts and is Available from ISO Central Secretariat
  - sales@iso.org



#### ISO 15489: February 5, 2002



- A Common International Language to Record and File Material in any Medium or Format
- Helps a Firm Systematically and Effectively Improve its Recordkeeping
  - Specifies how firms implement records management program
  - Improves global records management
- Supports Business Principles Behind Records Management
  - Senior management can identify tangible benefits like reduced costs and better managed risks
- Demonstrates Why Good Records Management Practice is Essential to Create, Capture and Use Information

#### **Satisfying CROMERRR**



- Establish Good Electronic Recordkeeping
- Use Procedures and Controls that Ensure Data Integrity
- Maintain e-Sigs Including Renewing the Sig Certificate
- Retain Complete Audit Trail for Same Retention Period
- Detect Altered or Deleted Records
- Generate of e-Copies for EPA Review
- Retain Link Between e-Records and e-Sigs



#### References



- View Comments:
  - http://www.epa.gov/cdx/cromerrr/propose/index.html
- EPA's Office of Environ Info:
  - http://www.epa.gov/oei
- EPA's CDX:
  - http://www.epa.gov/cdx/
  - Connie Dwyer & Matt Leopard @202/260-5300
- EPA's Draft 2000 Strategic Plan
  - http://www.epa.gov/ocfopage/plan/draftplan.htm
- CROMERRR:
  - David Schwartz & Evi Huffer @ EPA/OEI
  - Schwartz.David@epa.gov 202/260-2710
  - Huffer.Evi@epa.gov 202/260-8791







# Measures of Quality System Implementation

Louis Blume, US EPA, Great Lakes
National Program Office

Judy Schofield & Molly Middlebrook,
DynCorp, a CSC company



# Stages of Quality System Implementation



- Quality programs are not implemented with the stroke of a pen upon the approval of a Quality Management Plan
- Functional quality programs do not just happen - they evolve



# Stages of Quality System Implementation Matrix



- X-axis = Degree of Implementation
  - Stage 1: 0-25%
  - Stage 2: 25-50%
  - Stage 3: 50-75%
  - Stage 4: 75-100%
- Y-axis = Characteristics, Actions, Attitudes, Keys to Success, and Size Aspects/Scale Implications



# Value of Defining Stages of Implementation



- Provides a metric to measure success
- Emphasizes the fact that good programs take time and continuously improve
- Illustrates a quality continuum





# Value of Defining Stages of Implementation Continued



- Facilitates discussion of quality systems by placing specific characteristics in context, e.g., actions, attitudes, keys to success, etc.
- Establishes realistic expectations





#### Kubler-Ross



#### Stages of grief:

- Denial (this isn't happening to me!)
- Anger (why is this happening to me?)
- Bargaining (I promise I'll be a better person if...)
- Depression (I don't care anymore)
- Acceptance (I'm ready for whatever comes)



Stage 1: 0-25%		
Characteristics	•External pressure forces development of QS •One person appointed to QA •No infrastructure	
Actions	<ul> <li>Appoint additional QA personnel</li> <li>Draft QMP</li> <li>Harness enthusiastic people showing initiative</li> </ul>	
Attitudes	<ul> <li>•Management does not see importance of QA</li> <li>•Minimal understanding throughout organization</li> <li>•Lack of commitment by personnel</li> </ul>	
Keys to Success	<ul> <li>Develop generic QMP (not too prescriptive)</li> <li>Do not have QAM's name on QMP</li> <li>Bring enthusiastic people onto QA team</li> </ul>	

## Size Aspects/Scale Implications – Stage 1: 0-25%



- QA personnel not always truly independent
- QMP could be more generic gets you over the hump
- Small organization can develop a more prescriptive QMP



Stage 2: 25-50%		
Characteristics	•QMP approved	
	•QAPPs developed for some projects	
	•Polarization of QAM and POs	
Actions	•QA staff identify delinquencies & try to fill gaps	
	•Training	
	•Good opportunity for external MSRs	
	•Develop inventory of projects/expenditures	
Attitudes	•Most see QA as bureaucratic exercise	
	•Difficult exchanges between QA staff & POs	
	•Problem: "How will my QAM fix this?"	
Keys to	•Management takes ownership	
Success	•Develop inventory of projects/expenditures	
	•Build on positive behavior & ignore nay-sayers	

# Size Aspects/Scale Implications – Stage 2: 25-50%



- Larger organizations tend to develop decentralized programs because it is easier to deal with multiple stages of success
- In larger organizations, QAM will often burn out while dealing with polarization of QAM and Project Officers
- Small organizations can get through this stage much easier



Stage 3: 50-75%		
Characteristics	•QMP approved and partially implemented •QAMs involved in management meetings •Management begins to ask QA questions	
Actions	•POs employ systematic planning for all projects •QA staff involved in project planning •Inventory of projects 100% implemented	
Attitudes	•Most staff believe QA provides value •QAM feels like part of the team and not tattle-tail •Problem: "How will we fix this?"	
Keys to Success	•QA staff must stay involved at project-level •Recognize and reward QA successes •Will not work if management makes people do it	

# Size Aspects/Scale Implications – Stage 3: 50-75%



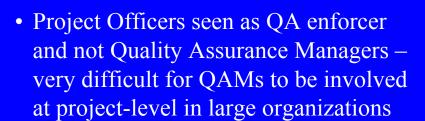
- Large organizations experience difficulties taking inventory of projects/expenditures
- QAMs in large organizations experience difficulties participating on the project-level





Stage 4: 75-100%		
Characteristics	•Quality system is comprehensive	
	•QA is a component of daily activities for all staff	
	•Peer review & info quality key parts of QS	
	•Managers are actively involved and well-trained	
Actions	•Use QA training & experience in hiring criteria	
	•Staff use "we" terms instead of "you" terms	
	Continually re-evaluate	
Attitudes	•Staff seek out QA personnel for assistance	
	•Staff are empowered to improve quality	
	•Staff reveal QA concerns - know they'll be heard	
Keys to	•QAM integral part of project development	
Success	•PO seen as enforcer and not QAM	
	•Hire people with positive QA attitudes	

# Size Aspects/Scale Implications – Stage 4: 75-100%



QAM serves as organization's management consultant



### **Critical Goal**



Quality programs are implemented at the staff-level with management encouragement and support.





# How does your organization compare? – We need your input!



Analyze your organization against the QA matrix handout...

- Where does my organization fall in this matrix?
- What aspects are missing from this matrix? How can it be improved?
- Where do I struggle the most with my QA system implementation?

# Next Steps in Developing the Stages of QS Implementation



Develop an informal workgroup to enhance this matrix for stages of QS implementation





#### Comments



Please send all comments and questions to:

- Louis Blume, GLNPO QAM 312-353-2317; Blume.Louis@epamail.epa.gov
- Judy Schofield, CSC/DynCorp 703-461-2027; jschofield3@csc.com
- Molly Middlebrook, CSC/DynCorp 703-461-2245; mmiddlebrook@csc.com



# Office of Pesticide Programs' Quality Assurance Program

Betsy Grim
Director of Quality Assurance



### **OPP's Mission**

Protect human health and the environment from unreasonable adverse effects from the use of pesticides.



### OPP is Unique within EPA

- Licensing Program
- Has authority to collect data
- Pesticide Label is the Law
- States have primary enforcement responsibility



### OPP is Unique-cont

- Largest Office in EPA
- Interface with AA
- Work in concert with OGC and OECA
- Work outside-advisory committees
   -interagency cooperation



### **Primary Statutes**

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) 1947, amended 1988

Federal Food, Drug, and Cosmetic Act (FFDCA)

Food Quality Protection Act (FQPA) 1996

Pesticide Registration Improvement Act (PRIA)



#### **FIFRA**

- Registration of Pesticides
- Evaluation of health and environmental data
- Balancing of risk and benefits
- Label is the law



### **FFDCA**

- Establishes tolerances for maximum residues of pesticides in food
- Applies tolerances
- Designates responsibility for monitoring to FDA and U.S. Dept to Agriculture



### **FQPA**

- Amended both FIFRA and FFDCA
- Tougher safety standard "reasonably certainty of no harm"
- New concepts
  - -aggregate exposure
  - -cumulative risk
- Consumer right-to-know



## Pesticide Registration Improvement Act- PRIA

- Discussions held over the past 10 years
  - EPA
  - Public Interest Groups
  - Registrant/Trade Associations

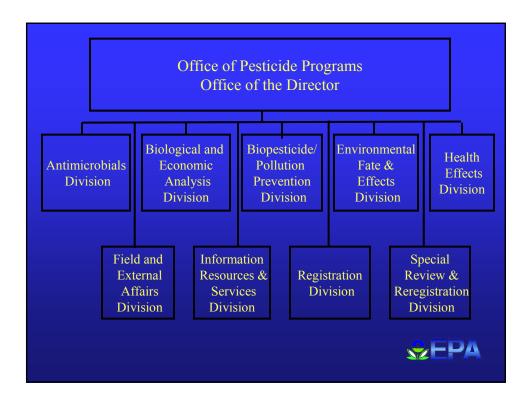
Signed by President Bush on January 23, 2004 as part of the Consolidated Appropriations Act

Goes into effect on March 23, 2004

Authority to collect fees for Pesticide Registration

#### PRIA cont.

- Reduced timeframes and greater predictability for registration decisions
- More accountability for registration decisions
- Greater assurance that FQPA and reregistration deadlines are met
- More stable, predictable, and augmented funding for the pesticide program



## Biological and Economic Analysis Division Laboratories

- Analytical Chemistry Branch
- Environmental Chemistry Branch
- Antimicrobials and Plant Pathogens Branch
- Microarray Research Laboratory

## Analytical Chemistry Branch

- Validates analytical methods for detecting pesticide residues in food.
- Provides technical support to Regions, States and other Federal Agencies
- Maintains Repository of analytical standards
- Provides Support to Antimicrobial Division
- Develops New Methods

### **Environmental Chemistry Branch**

- Assesses analytical methods for detecting pesticide residues in soil and water.
- Develops methods
- Supports Dioxin Exposure Initiative
- Provides technical support to Regions, States and other Federal Agencies

# Antimicrobials and Plant Pathogens Branch

- Conducts laboratory efficacy testing of antimicrobial pesticides
- Research and Development of Existing and New Methods for Evaluating the Efficacy of Antimicrobial Products Designed to Treat Building Surfaces and Material Contaminated with Bioterrorism Agents

### Microarray Research Laboratory

- Integrates the recent advances in the field of genomics with current microbiological techniques for testing the effectiveness of antimicrobial agents
- Analyzes genomic changes in pathogenic bacteria in response to exposure to antimicrobials

### Responsibilities of OPP

- Register new pesticide active ingredients
- Review emergency exemption requests
- Reregister pesticides
- Reassess tolerances existing prior to FQPA
- Protect groundwater and endangered species
- Conduct pesticide applicator and worker protection programs
- Promote environmental stewardship



### Regulatory Decisions affect

- 10-12 major international pesticide producers (100 small producers)
- 2,200 pesticide formulators
- 17,000 distributors
- 33,000 commercial pest control firms
- 1.9 million farms
- Several million professional users
- 104 million households



## OPP's Quality Assurance Program



# Follows Agency wide Quality System

- EPA Order –May 2000
- EPA's Quality System provides policies, principles and responsibilities for managing quality-related activities and;
- The framework for planning, implementing, and assessing work performed by the Agency



# It is 1997 and Time to revise the Quality Management Plan (QMP)

- OPP Reorganization
- QMP-Sept 1993



# Time to Revise the QMP

- Made a decision to include the entire pesticide program.
- Before
  - Covered OPP's three laboratories
  - Contracts, grants and IAGs with environmental data
- Now
  - covers all environmental data used in risk assessments (including data bases and models)



# Formed the OPP QA Team

- Representation from all of OPP's Divisions
- Mission Statement
- Identified responsibilities
- Language for performance agreements
- Decided on our first tasks



# OPP's QA TEAM VISION STATEMENT

 Through a keen understanding of the principles of quality assurance and with our individual skills and team effort, we will create an environment that continually evaluates and improves work processes and products to meet our needs and the needs of our customers, and to ensure that all environmentally related measurements supported by the OPP are of known and acceptable quality and can readily be used to support regulatory decision-making.



# Responsibilities of OPP's QA Officers

- Assure process for Peer review of risk assessments
- Assure that SOPS and SEPs reflect current scientific review
- Assure process for documentation of models and data bases
- Maintain model library (reproducible)



# Responsibilities cont.

- Review all contracts, grants and IAGs
- Prepare Quality Assurance Project Plans
- Prepare Annual Report and Work Plan
- Assist OPP Director of Quality Assuranceaudits internal and external



# QAO's Performance Standards

- Establishes
- Implements and
- Maintains
  - The quality assurance program within the Division



## Decided our First Tasks

- Revise OPP's Quality Management Plan
- Address Consistency across and within Divisions
- Address Quality of Data Bases
- Address Quality of Models



# First task-Revise the QMP

- Decided to have one major document following agency guidelines for QMPs
- Developed an appendix for each Division following same guidance
- Developed an appendix for the Regions
- Approved OEI-May 2000



# Second Task- Address Consistency

- Reorganization resulted in similar functions occurring in different Divisions
- Inconsistencies identified in OEI audit



# This is where the fun began

- We would do a cross walk of data guidelines
- Determine which series of guidelines crossed over the most Divisions
- Write an SOP for Review of this series



## and -This is what we found

- Multiple lists of guidelines existed
- Few guideline list guardians were aware of the others
- Few people were aware there was a master list (available by request only)



## At the same time-harmonization

- Harmonization with OPPTS (with our sister program –Toxics)
- Harmonization with OECD and NAFTA and
- We were revising our entire guideline section in the CFR Part 158



# **Product Properties SOP**

- Crossed over FIVE Divisions
- Formed work group
- Approved by OPP Management
- On OPP's intranet
- Waiting approval for internet



## Third task-Address Data Bases

- Inventory- where, name, owner
- Developed format for documentation included: name, acronym, purpose, assessment of accuracy, completeness, and addressed *UNCERTAINTY* of data
- Developed guidance for future data base development



#### Forth task-Address Models

- Inventory-where, name, owner
- Developed format for documentation
- Working on guidance for future model development



# Model Documentation

- Model Name
- Version Number
- QA Summary
- Date
- Model Developer
- Model Contact



# Model Documentation cont.

- Model Type
- Historical Insight
- Method of Version Control
- List of Prior Model Versions
- Model Calibration Reports
- Model Evaluation Reports



#### Model Documentation Cont.

- Peer Review Report Summary
- Model Access Mechanism
- Intended Use of Output
- Regulatory Context, if any
- Process for archiving and documentation



## Model Evaluation

- Developed according to the principles of sound science
- Choice of model is supported by the quality and quantity of available data
- Reasonably approximated the real system of interest
- Performs the required task while meeting the objectives set by QA project planning



#### **Best Practices**

- Conduct peer review
- Assess data quality
- Perform corroboration
- Perform sensitivity and uncertainty analysis



# Challenges ahead for QA in OPP

- Peer Review- Assessment Factors
- *In vitro* testing
- Endocrine disruption
- Addressing Uncertainty
- EPA Information Quality Guidelines



# ETD QA Core Team: An Eloquent Solution to a Complex Problem

Thomas J. Hughes
Experimental Toxicology Division
QA and Records Manager
EPA Annual QA Meeting, Tampa, FL
April 16, 2004



# Research and Development at EPA



- 1,950 employees
- \$700 million budget
- \$100 million extramural research grant program
- 13 lab or research facilities across the U.S.
- Credible, relevant and timely research results and technical support that inform EPA policy decisions





# Making decisions with sound science requires..

- Relevant, high quality, cutting-edge research in human health, ecology, pollution control and prevention, economics and decision sciences
- Proper characterization of scientific findings
- Appropriate use of science in the decision process

# Research and development contribute uniquely to..

- Health and ecological research, as well as research in pollution prevention and new technology
- In-house research and an external grants program
- Problem-driven and core research



# High Priority Research Areas



- Human Health
- Particulate Matter
- · Drinking Water
- · Clean Water
- Global Change
- Endocrine Disruptors
- Ecological Risk
- Pollution Prevention
- Homeland Security



# National Health and Environmental Effects Research Laboratory, Experimental Toxicology Division (ETD), RTP, NC

 NHEERL is in ORD, and has nine research divisions. ETD conducts research on PM, water, metals and pesticides, in pulmonary, immunotoxicology, cardiovascular and pharmacokinetics research.



#### **PURPOSE**

Develop and implement a QA
 Core Team for the Experimental
 Toxicology Division (ETD), which
 has 120 Scientists, including 40
 Students and Post Docs, and
 conducts 55 research studies per
 year, with one QA Manager.



# Challenge

- · One QA Manager, Tom Hughes.
- 55 research studies per year.
- 10 studies are QA 1, 2 (WTC, U.S. Air Force Dioxin Study, drinking water research for EPA Office of Water mandated by U.S Congress).
- 30 audits, Technical System Reviews, and surveillances per year.



#### **Conclusion**

- QA workload was too extensive for one QA Manager to accomplish by himself.
- Other NHEERL Health QA Managers were not always available to assist Tom Hughes.
- In 2003, ETD Management granted permission to form an eight-member ETD QA Core Team.



#### Charter for QA Core Team

- Members would assist ETD QA Manager with audits, TSRs and surveillances.
- 2. Members would be taught QA techniques in periodic meetings.
- 3. Members would assist QA Manager for a maximum of two weeks per year, if assistance did not interfere with their lab research.
- 4. Two members per year would attend national EPA QA Meetings.
- Membership would be reviewed yearly in January.



## ETD QA Core Team Members for 2003

- Pulmonary Toxicology Branch
   Mette Schladweiler, Lenny
   Walsh, Najwa Coates.
- 2. Pharmacokinetics Branch
  Brenda Edwards, Carol Mitchell,
  Tracey Ross, Karen HerbinDavis.
- Immunotoxicology Branch Don Doerfler.



# Strengths of a Team Concept

- Team effectively means
   Together Everyone Accomplishes More.
- An eight-member Team gave the QA
   Manager diversity in skills and training in
   Members, and the flexibility to use different
   Members on multiple assignments at the
   same time.
- 2. "None of us is as smart as all of us." Roy Disney, 1966.
- "There are more of them than us." Walt Patterson, 2004.



# Benefits to the Division from the ETD QA Core Team

- Members were trained in QA techniques, which helped their labs keep better records, and thereby be successful in internal and external reviews and audits.
- 2. Members became ambassadors for QA and Records Management in their Branches.
- 3. Provided career development opportunities to Team Members.



# Benefits to Management from the ETD QA Core Team

- Members only donated a maximum of two weeks to the Team, and only when their assistance did not interfere with their research.
- QA is a Agency requirement, which is being conducted by a TEAM, and not by one-three lab scientists.
- 3. A Team avoids conflict-of interests on review teams.



# Benefits to Members of the ETD QA Core Team

- Membership demonstrates leadership, which is very useful in annual performance reviews.
- Membership trains them in QA and records management, which makes their jobs easier.
- Exceptional performances are rewarded with cash and time-off awards.
- Members get the ability to travel to EPA QA Meetings, and present QA Data.



# Benefits to the QA Manager from the ETD QA Core Team

- He has a trained eight-member Team that can assist him with required Agency QA activities.
- 2. Members make it easier for him to conduct audits.
- 3. Members assist him with QA reports.
- Members assist the QA Manager with their knowledge, and help him to more effectively audit studies.



# Topics for QA Core Team Training

- Technical Systems Review (TSR) checklists
- 2. Surveillance Checklists
- 3. Preaudit Checklists
- 4. Audit, surveillance, TSR training
- 5. Professional conduct during an audit/review/surveillance
- Agency QA activities, and record keeping requirements



# Changes to the ETD QA Core Team in 2004

- Najwa Coates, a pulmonary toxicologist, left the Team. She was replaced by Jerry Highfill, a senior statistician.
- 2. Due to three modeling projects that were planned for review in 2004, Kristin Isaacs, a UNC Post-doc modeler, joined the Team.
- 3. All other Members from 2003 stayed on the Team, which was very encouraging, because they are ALL volunteers.



# ETD QA Core Team: Recognition of Accomplishments

- Recognized by Brenda Culpepper, the DQA for NHEERL, as a BEST PRACTICE, during a QMSA of ETD in August 2003.
- Management submitted the QA Core Team for an EPA Bronze Award in 2004.
- 3. There is competition within the Division to become a Member.



# Things that Make the ETD QA Core Team Successful

- 1. Very strong Management support.
- Members are from across the Division, and were selected by the QA Manager and Management.
- 3. A schedule is provided to all Staff at the beginning of the year.
- 4. Members are rewarded for exceptional service.
- 5. Management is keep informed of QA Core Team activities and successes.



# Benefits of a QA Team Approach verses the Use of QA Assistants

- 1 QA training is faster and more efficient for the QA Manager.
- 2 No Team Member has to donate large amounts of time per year.
- 3 A Team provides flexibility of scheduling to the QA Manager. Changes in assistance can be made very quickly and easily.



# Benefits of the ETD QA Core Team to the Division

- There now exists a large number of trained QA auditors in the Division who can conduct required Agency QA audits and reviews.
- 2. These Division QA auditors are also scientists, so they fully understand the science they are auditing.
- 3. Division record keeping has improved.
- The benefits and usefulness of QA and record keeping activities are now more fully appreciated throughout the Division.



# Suggestions on Why Your Research Organization Should Form a QA Team

- Contingency Planning What happens if your QA Manager gets detailed, leaves for another job, gets sick or retires?
- A Team, large or small, makes the QA Agency requirements easier to conduct, and much more efficient.
- 3. Management looks better in external reviews with a strong QA Team.
- Teams are extremely useful for auditing and reviewing data from large high-profile studies.



#### **CONCLUSIONS**

- 1 The ETD QA Core Team has made data and record keeping from EPA research studies more reliable and defensible.
- 2 Required reviews of research data in ETD are now conducted more efficiently.
- 3 The formation and implementation of the ETD QA Core Team was a simple, yet eloquent, solution to a complex QA and data management problem.



THANK YOU

ETD QA CORE TEAM

You Done GOOD!